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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,180	10/11/2006	Ken Shortman	19975	4755

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EXAMINER	
LONG, SCOTT	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
12/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,180	SHORTMAN ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/21/2009*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10 and 13-29* is/are pending in the application.

4a) Of the above claim(s) *13-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application.
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2009 has been entered.

Claim Status

Claims 1, 3, 5-10 and 13-29 are pending Claims 4, 6 and 11-12 are cancelled. Claim 1 is amended. Claims 28-29 are withdrawn by the applicant. However, claims 13-27 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1, 3 and 5-10 are under current examination.

Priority

This application claims benefit as a 371 of PCT/AU04/01840 (filed 12/23/2004) which claims priority from Foreign Application, AUSTRALIA 2003907195 (filed 12/24/2003). The instant application has been granted the benefit date, 24 December 2003, from the Foreign Application, AUSTRALIA 2003907195

RESPONSE TO ARGUMENTS

35 USC § 102

Claim Rejections - 35 USC § 112

The rejection of claims 1, 3 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Maliszewski (Pathol. Biol. 2001; 49: 481-483) is withdrawn in response to the applicant's claim amendments.

The applicant's claim amendments have introduced limitations directed to "delaying onset of diabetes." The cited art does not teach these limitations.

Therefore, the examiner hereby withdraws the rejection of claims 1, 3 and 7-9 under 35 U.S.C. 102(b) as being anticipated by Maliszewski.

35 USC § 112, 1st paragraph (enablement)

The rejection of claims 1 and 3-12 under 35 USC 112, 1st paragraph (lack of enablement) is withdrawn in response to the applicant's claim amendments.

The applicant's arguments have been fully considered and are persuasive. The applicant has amended the claims to change the scope of the claimed invention to "delaying onset of diabetes." Enablement of this claim amendment is supported by the state of the art and the instant specification.

Therefore, the examiner hereby withdraws the rejection of claims 1 and 3-12 under 35 USC 112, 1st paragraph.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morin et al. (Clinical & Experimental Immunology. 134(3): 388-395; published online 24 Nov 2003).

Claim 1 is directed to a method for delaying onset of diabetes in a subject said method comprising administering to said subject Flt-3L [Flt-3 Ligand] in an amount effective to increase a sub-type of non-activated, immature and tolerogenic DC selected from Plasmacytoid DC, $CD8^+$ DC or their equivalents thereby inducing or maintaining immune tolerance in said subject which delays onset of diabetes.

Morin et al. teach transplantation of *in vivo* Flt-3L cultured-dendritic cells into non-obese diabeteic (NOD) mice delays diabetes development in these recipient NOD mice (Title & Abstract). Furthermore, Morin suggests "[w]e hypothesize that flt-3L-DC represent the *in vitro* counterparts of a subset, or a maturational state, of DC that is defective in NOD mice and cannot be derived easily from BM progenitors cultured with GM-CSF + IL-4....Specific stimulation of this subset of DC may open new possibilities of therapeutic intervention to prevent diabetes onset" (page 294, col.1, last parag.). Furthermore, Morin teaches, "According to the authors, the protection was due to tolerogenic presentation of islet antigens by transferred DC." (page 388, col.2, lines 2-3). Therefore, Morin conceived of the idea of stimulating dendritic cells *in vivo* with Flt-3L to increase a sub-type of non-activated, immature and tolerogenic DC in order to delay the onset of diabetes.

Morin does not specifically state what this "therapeutic intervention" might be. A skilled artisan could quickly conceive of two possibilities from the cited art: (1)

transplantation of Flt-3L stimulated dendritic cells or (2) administration of recombinant Flt-3L. The suggestion of Morin would encompass the claimed invention.

Claim 3 is directed to the method of claim 1 wherein the Flt-3L is co-administered with a cytokine. Morin teaches co-stimulation of dendritic cells with Flt-3 Ligand, GM-CSF and IL-6 (page 389, col.1, Generation of DC section).

Claim 5 is directed to the method of claim 3, wherein said co-administration is sequential administration. The specification indicates that "sequentially means within nanosecond, seconds, minutes, hours, days or weeks or other time intervals" (page 11, lines 24-25). Morin teaches stimulation of dendritic cells with Flt-3 Ligand, GM-CSF and IL-6 over a period of weeks (page 389, col.1, Generation of DC section).

Claim 6 is directed to the method of claim 3, wherein said co-administration is simultaneous administration. Morin teaches simultaneous, co-stimulation of dendritic cells with Flt-3 Ligand, GM-CSF and IL-6 (page 389, col.1, Generation of DC section).

Claim 7 is directed to the method of claim 1 wherein the subject is a human, non-human primate, livestock animal, laboratory test animal, a companion animal, a captured wild animal or an avian species. Morin teaches methods which use a laboratory mouse, but also suggest treatment of humans.

Claim 8 is directed to the method of claim 7, wherein the subject is a human. Morin suggest applying their method to humans (page 394, col.1, last sentence).

Claim 9 is directed to the method of claim 1, wherein the Flt-3L is derived from the same species to which it is administered. In particular, Morin suggests treatment of

humans. The Flt-3L used by Morin is human Flt-3L. Therefore, Morin suggests administering a Flt-3L derived from the same species to which it is administered.

Claim 10 is directed to the method of claim 1, wherein the Flt-3L is derived from a different species to which it is administered. In particular, Morin teach models where human Flt-3L is delivered to mice. Therefore, the Flt-3L is derived from a different species to which it is administered. Furthermore, Morin has demonstrated that human Flt-3L is sufficiently homologous the mouse Flt-3L to function in mice.

Morin et al. does not teach an explicit embodiment of the claimed method where Flt-3L is administered to a subject to delay onset of diabetes.

However, Morin et al. suggest a therapeutic intervention where Flt-3L is administered to a subject to delay onset of diabetes.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to administer Flt-3L to a subject to delay onset of diabetes.

The person of ordinary skill in the art would have been motivated to administer Flt-3L to a subject to delay onset of diabetes. Morin has shown that Flt-3L can mature a population of dendritic cells such that these cells are capable of delaying onset of diabetes in a diabetic mouse model. Furthermore, Morin utilized recombinant human Flt-3L in their experiments. Additionally, Morin suggest using this knowledge for therapeutic intervention to prevent diabetes onset. Additionally, Morin has demonstrated that recombinant human Flt-3L can be taken up by dendritic cells. Therefore, a skilled artisan in the possession of Morin would be motivated to administer human Flt-3L to a human subject to delay onset of diabetes. Such a method is the

most logical and simple method suggested by Morin. Administration of recombinant human proteins to human subjects for the treatment of disease is well known and practiced among skilled artisans. The examiner concludes that to a skilled artisan, with the knowledge of the art of utilizing recombinant proteins, administering recombinant human Flt-3L to a human subject to delay onset of diabetes would be the most obvious application of the discovery of Morin.

An artisan would have expected success, because Flt-3L has been shown to mature a population of dendritic cells such that these cells are capable of delaying onset of diabetes in a diabetic mouse model.

Therefore the method as taught by Morin et al would have been *prima facie* obvious over the method of the instant application.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/
Patent Examiner, Art Unit 1633